Is High-Voltage Lead Integrity Measurement Adequate During Defibrillator Generator Replacement?

RAHUL DOSHI, MD, FHRS, STEVEN CEBALLOS, CVT and FAUSTO MENDEZ, CVT

St. Jude Medical Center, Fullerton, CA
University of California, Irvine, CA
Fullerton Cardiovascular Medical Group, Fullerton, CA

ABSTRACT. The necessity for defibrillator testing at the time of implant or generator replacement is widely debated. The need for administering a shock at time of implant is lessened by the use of high-voltage integrity checks commonly employed by all device manufacturers. We report a case of a patient with a lead under safety advisory (St. Jude Riata 1580) and known externalization of conductors with no prior electrical abnormalities who underwent routine generator replacement. After the generator replacement, the high-voltage integrity check was normal, but during defibrillator testing the device was unable to deliver high-voltage therapy after successful induction of ventricular fibrillation. This was repeated after reinterrogation of the device, again showing normal high-voltage integrity and once again it failed to deliver life-saving therapy. Both failures were a result of a low impedance, and subsequent interrogation revealed non-detectable impedance consistent with a short in the high-voltage circuit. Lead analysis revealed a short in the high-voltage circuit not related to externalization of conductor wires. This case illustrates the importance of delivering an actual high-voltage shock to determine the circuit integrity for a defibrillator system at time of implant or replacement.

KEYWORDS. defibrillation threshold, implantable cardioverter-defibrillator, Riata.

Introduction

Implantable cardioverter-defibrillator (ICD) placement is widely utilized in high-risk groups for primary and secondary prevention of sudden cardiac death. The need for defibrillator testing, once considered an essential part of the implant, is now widely debated. Advocates of defibrillator testing cite the need for determining the safety margin for successful defibrillation, given that defibrillation is probabilistic in nature. Opponents cite the increased mortality associated with the induction of ventricular fibrillation (VF), anesthesia requirements, training requirements, and the increased safety margins afforded by higher output devices. Historically, the high-voltage (HV) circuit integrity was confirmed by measurement of normal impedance during an actual shock. However, this has been replaced by HV integrity testing that uses the measurement of current resistance through the HV circuit without delivering a painful shock. Such testing can be done without anesthesia and is performed during routine follow-up and through daily out-of-clinic impedance monitoring. Impedance measurements are stored and reported remotely via most remote monitoring systems. This type of measurement is another potential reason why defibrillator testing is not uniformly recommended. The increased failure rates of small caliber ICD leads requires rigorous monitoring of the HV integrity to ensure the availability of life-saving therapy. We present a case that illustrates the need for actual shock delivery to assess lead integrity.
Case report

A 77-year-old male with a history of prior myocardial infarction, ischemic cardiomyopathy, and dual-chamber ICD (Epic Plus DR model V-239, St. Jude Medical, Sylmar, CA) presented for routine generator replacement. This device is not capable of HV integrity checks without delivering a 12-volt HV shock. The patient had a dual-coil lead under a Class I safety advisory (Riata model 1580, St. Jude Medical) with known externalization of conductors confirmed previously by fluoroscopy. The patient was implanted originally for primary prevention and was not pacer dependent. The original defibrillation testing demonstrated a shock impedance of 44 ohms. The previous device did not have HV integrity test capability without administering a shock. The patient had relatively preserved left ventricular ejection fraction at 45% and no recent evidence of congestive heart failure (CHF). Both the lead and generator were 70 months old. The patient underwent routine generator replacement (Fortify model 2231, St. Jude Medical) capable of HV integrity checks. After replacement, all measurements through the device were normal, including an HV integrity check of 39 ohms, with a normal range 30–55 ohms for a dual-coil system (St. Jude Medical, personal communication).

The patient was prepared for defibrillation testing. He was already under anesthesia, and transthoracic defibrillation was available. A low voltage (1 J) shock on T wave was utilized to initiate VF and was successful. The impedance measurement for the 1-J shock is not measured. The device appropriately detected VF but was unable to deliver an HV shock at 20 J. The patient was promptly defibrillated externally. Analysis of the device revealed a failure in the system integrity. The programmer was rebooted, and the device was reinterrogated after all connections and lead integrity in the pocket was confirmed. All device measurements through the device were again normal, including an HV integrity measurement of 35 ohms. Once again, VF was successfully initiated with a 1-J shock, and again the device was unable to deliver a 20-J shock, and the patient was defibrillated externally. Interrogation again revealed a system integrity error, and the programmer was again rebooted. Interrogation of the device now revealed low impedance in the HV circuit of <10 ohms.

The patient was transferred to the operating room and underwent successful transvenous lead extraction. Visual inspection of the extracted defibrillator lead revealed externalized conductors (Figure 1). The lead and defibrillator generator were both sent back to St. Jude Medical for analysis. The patient underwent successful reimplantation of a dual-chamber ICD system (Fortify model CD2231-40Q and Durata model 7120Q, St. Jude Medical) and had an uneventful recovery.

Detailed inspection and analysis revealed the externalized conductor cables as visualized in several locations with the ethylenetetrafluoroethylene (ETFE) coating intact. However, internal abrasion of conductor cables was noted beneath the distal end of the superior vena cava (SVC) coil with one of the right ventricular (RV) shock cables melted, suggesting the likely location of the failure in the system integrity and low impedance measurement (Figure 2).

Discussion

This case illustrates a failure of HV integrity testing after routine generator replacement, and subsequent repeat failure of such testing even after a demonstrated failure in delivering therapy secondary to a short in the HV circuit. After the second failure, the HV integrity testing revealed a shock coil impedance of <10 ohms.

Recently, there have been growing concerns regarding ICD systems with small-diameter leads. Several reports have demonstrated high rates of lead failures for both the Medtronic Sprint Fidelis lead and the St. Jude Medical Riata lead. These series have also characterized the type of failures and presentations, which include inappropriate sensing with inhibition of pacing, inappropriate shock therapy, increases in pacing threshold, or change in impedance, including HV measurement or pacing impedance. These abnormalities could be detected before the need for life-saving therapy. For this reason, many experts reinforce the importance of remote monitoring, especially in these patient populations at high risk for lead failure. Remote monitoring would include frequent measurement of the HV integrity circuit. However, this case illustrates that a malfunction may not necessarily be detected by HV integrity checks during routine replacement.

Figure 1: Explanted 1580 Riata lead. The arrows demonstrate areas of externalized conductor cables (blue). There were three areas of externalized conductors seen on visual inspection, the most obvious just proximal to the right ventricular coil. This portion was seen on prior fluoroscopic visualization.
integrity tests and thus not provide a warning before therapy is required. Recently, Shah et al.\(^1\) have described a case in which a Riata lead had a similar abnormality detected only after an inappropriate shock for supraventricular tachycardia was attempted. Subsequent measurement of the HV integrity was normal. The algorithm for this device measures the current prior to shock delivery, and aborts therapy if excessive current is delivered. This does not affect subsequent HV integrity testing (St. Jude Medical, personal communication). This case and ours illustrate the limitations of relying on HV integrity testing without shock administration. Ricci and colleagues\(^1\) have estimated in a series of over 400 patients with the Sprint Fidelis lead that electrical abnormalities seen on remote monitoring could have predicted failures in only 50% of patients. A significant concern regarding failures for the Riata lead is that the incidence of electrical abnormalities is quite low\(^1\) and thus may go undetected. In a series of over 7,000 patients implanted with the Riata lead, the incidence of conductor fracture was reported at 0.09% and insulation damage at 0.13% over a mean follow-up of more than 22 months.\(^1\) At this time, there are no recommended strategies for management of these leads with known externalized conductors from the manufacturer.

Defibrillator threshold testing (DFT) at the time of initial device implant or replacement is occurring less today given the ongoing debate regarding its necessity. Stefano et al.\(^1\) have reported that physicians participating in an Italian registry (The Assessment of Long-term Induction clinical ValuE) perform routine defibrillator testing a third of the time. Blatt and colleagues\(^1\) analyzed the Sudden Cardiac Death in Heart Failure Trial database and failed to see a difference in outcomes between ICD recipients with low compared with high DFTs. In fact, most mortality estimates are similar with DFT and no-DFT strategies, and only a potential benefit is seen in patients with a high annual risk of sudden death greater than 5% per year.\(^1\) However, the debate on whether or not to perform routine DFT testing is related to the need for determining the actual DFT or demonstration of an adequate safety margin. The potential need for routine assessment of lead integrity is a completely different factor that introduces a new argument for the routine use of defibrillator testing or delivering an HV shock. This type of testing might seem prudent in leads that are known to have higher failure rates, but the same argument could be applied to all ICD lead systems.

DFT testing has been demonstrated to have an extremely low risk of complications. Birnie et al.\(^1\) have reported the safety of DFT testing in Canada in over 19,000 implants. They report a total of three deaths, five strokes, and 27 periods of long resuscitation. This was with traditional DFT measurement. Upper limit of vulnerability (ULV) testing offers an alternative method for measurement of the DFT\(^1\) and can be utilized for a completely “inductionless” implant.\(^1\) Alternatively, we propose that a commanded HV synchronized shock could be utilized for testing the system integrity with a low risk of VF induction. It seems prudent that all patients without a contraindication undergo either traditional DFT testing, ULV testing, or a commanded HV shock at the time of device replacement given the low additional risk associated with the procedure. Whether or not routine surveillance testing should be performed in certain high-risk patients with leads under a safety advisory still needs to be determined.

References


